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13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/424,629	Applicant(s) FOOTE ET AL.	
	Examiner Arun Chakrabarti	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 24-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Specification

1. Claims 19-23 have been canceled without prejudice towards further prosecution. Claims 10 and 24 have been amended.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

3. Claims 1-5 and 24-28 are rejected under 35 U.S.C. 102 (e) as being anticipated by Kamb (U.S. Patent 5,869,242) (February 9, 1999).

Kamb teaches a method of detecting a difference of one or more nucleotides between a nucleic acid molecule to be tested and a reference nucleic acid molecule and identifying a mutation (Abstract) , the method comprising:

subjecting the test nucleic acid molecule to base specific cleavage to generate oligonucleotide fragments (Claims 1-3 and 5 and Example IV, Column 6, line 50 to column 8, line 37);

separating the resulting oligonucleotide fragments based on mass by MALDI-TOF MS to produce a fingerprint of the oligonucleotide fragments comprising one or more peaks wherein a peak represents the mass of each fragment (Tables II and III and Example IV, Column 6, line 50 to column 8, line 37); and

identifying an altered peak relative to a reference nucleic acid molecule subjected to the same procedure wherein the presence of an altered peak is indicative of a difference of one or more nucleotides in the tested nucleic acid molecule (Claims 1 and 3 and Table II).

Kamb teaches a method wherein the nucleic acid molecule to be tested is amplified by a PCR prior to base specific cleavage (Column 4, lines 36-46 and Column 7, lines 39-54).

Kamb teaches a method wherein the base specific cleavage results in oligonucleotide fragments of from about 2 bases to about 1000 bases (Table III).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-7 and 24-30 are rejected under 35 U.S.C. 103 (a) over Kamb (U.S. Patent 5,869,242) (February 9, 1999) in view of Sutherland et al. (U.S. Patent 5,985,619) (November 16, 1999).

Kamb teaches the method of claims 1-5 and 24-28 as described above.

Kamb does not teach the method wherein the base specific cleavage is uracil specific and mediated by uracil-N-glycosylase.

Sutherland et al. teach the method wherein the base specific cleavage is uracil specific and mediated by uracil-N-glycosylase (Column 9, lines 4-29).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the uracil specific base cleavage mediated by uracil-N-glycosylase of Sutherland et al. into the mass spectrometry to assess DNA sequence polymorphisms of Kamb, since Sutherland et al. state, "The glycosylase useful in the present invention are those that specifically cleave unconventional bases, i.e., bases other than A,G,C or T in DNA and A,G,C and U in RNA. Glycosylases that specifically cleave unconventional bases such as N-& methylguanine, 3-methyladenosine, uracil and hypoxanthine are known to one of ordinary skill in the art. Preferred glycosylases include uracil N-glycosylase (UNG),

hypoxanthine-DNA glycosylase, and 3-methyladenine-DNA glycosylases I and II. The most preferred glycosylase in accordance with present invention is UNG. UNG is commercially available (Column 9, lines 4-19)." By employing scientific reasoning, an ordinary artisan would have combined and substituted the uracil specific base cleavage mediated by uracil-N-glycosylase of Sutherland et al. into the mass spectrometry to assess DNA sequence polymorphisms of Kamb in order to improve the sequencing of nucleic acids containing unconventional bases. An ordinary practitioner would have been motivated to combine and substitute the uracil specific base cleavage mediated by uracil-N-glycosylase of Sutherland et al. into the mass spectrometry to assess DNA sequence polymorphisms of Kamb in order to achieve the express advantages noted by Sutherland et al., of a preferred glycosylase UNG which is commercially available and useful to specifically cleave unconventional bases.

6. Claims 1-5, 10, 14 and 24-28 are rejected under 35 U.S.C. 103 (a) over Kamb (U.S. Patent 5,869,242) (February 9, 1999) in view of Koster (U.S. Patent 6,074,823) (June 13, 2000).

Kamb teaches the method of claims 1-5 and 24-28 as described above.

Kamb does not teach the method of using a computer capable of controlling a method of detecting mutation by MALDI-TOF MS.

Koster teach the method of using a computer capable of controlling a method of detecting mutation by MALDI-TOF MS (Column 5, lines 22-35).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a computer capable of controlling a method of

detecting mutation by MALDI-TOF MS of Koster into the mass spectrometry to assess DNA sequence polymorphisms of Kamb, since Koster states, "An additional advantage of mass spectrometric sequencing is that the identified masses can be registered automatically by a computer and, by adding the time coordinate, automatically aligned to sequences. Since the sequences so determined are memorized (i.e., saved to disk or resident in the computer memory), appropriate existing computer programs operating in a multitasking environment can be searching in the "background" (i.e., during continuous generation of new sequence data by the exonuclease mass spectrometric sequencer) for overlaps and generate contiguous sequence information which, via a link to a sequence data bank, can be used in homology searches, etc (Column 5, lines 22-35)." By employing scientific reasoning, an ordinary artisan would have combined and substituted a computer capable of controlling a method of detecting mutation by MALDI-TOF MS of Koster into the mass spectrometry to assess DNA sequence polymorphisms of Kamb in order to improve the sequencing of nucleic acids by automated procedures. An ordinary practitioner would have been motivated to combine and substitute a computer capable of controlling a method of detecting mutation by MALDI-TOF MS of Koster into the mass spectrometry to assess DNA sequence polymorphisms of Kamb in order to achieve the express advantages noted by Koster, of mass spectrometric sequencing by which the identified masses can be registered automatically by a computer and, by adding the time coordinate, automatically aligned to sequences and since the sequences so determined are memorized (i.e., saved to disk or resident in the computer memory), appropriate existing computer programs operating in a

multitasking environment can be searching in the "background" (i.e., during continuous generation of new sequence data by the exonuclease mass spectrometric sequencer) for overlaps and generate contiguous sequence information which, via a link to a sequence data bank, can be used in homology searches, etc

7. Claims 1-5, 8-9, 11-13, 24-28 and 31-32 are rejected under 35 U.S.C. 103 (a) over Kamb (U.S. Patent 5,869,242) (February 9, 1999) in view of Caprioli (U.S. Patent 5,808,300) (September 15, 1998).

Kamb teaches the method of claims 1-5 and 24-28 as described above.

Kamb does not teach the method of subjecting fragmentation products to further separation by the post source decay method.

Caprioli teaches the method of subjecting fragmentation products to further separation by post source decay method (Column 3, lines 9-11).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a further separation by post source decay method of Caprioli into the mass spectrometry to assess DNA sequence polymorphisms of Kamb , since Caprioli states, "The use of post-source decay techniques is shown in order to obtain sequence verification (Column 3, lines 9-11)." By employing scientific reasoning, an ordinary artisan would have combined and substituted a further separation by post source decay method of Caprioli into the mass spectrometry to assess DNA sequence polymorphisms of Kamb in order to improve the sequencing of nucleic acids. An ordinary practitioner would have been motivated to

combine and substitute a further separation by post source decay method of Caprioli into the mass spectrometry to assess DNA sequence polymorphisms of Kamb in order to achieve the express advantages, as noted by Caprioli, of a method which is used in order to obtain sequence verification.

8. Claims 1-5, 10, 14 , 16 and 24-28 are rejected under 35 U.S.C. 103 (a) over Kamb (U.S. Patent 5,869,242) (February 9, 1999) in view of Koster (U.S. Patent 6,074,823) (June 13, 2000) further in view of Sutherland et al. (U.S. Patent 5,985,619) (November 16, 1999).

Kamb in view of Koster teach the method of claims 1-5, 10, 14 and 24-28 as described above.

Kamb in view of Koster do not teach the method wherein the base specific cleavage is uracil specific and mediated by uracil-N-glycosylase.

Sutherland et al. teach the method wherein the base specific cleavage is uracil specific and mediated by uracil-N-glycosylase (Column 9, lines 4-29).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the uracil specific base cleavage mediated by uracil-N-glycosylase of Sutherland et al. into the computerized mass spectrometry to assess DNA sequence polymorphisms of Kamb in view of Koster, since Sutherland et al. state, "The glycosylase useful in the present invention are those that specifically cleave unconventional bases, i.e., bases other than A,G,C or T in DNA and A,G,C and U in RNA. Glycosylases that specifically cleave unconventional bases such as N-& methylguanine, 3-methyladenosine, uracil

and hypoxanthine are known to one of ordinary skill in the art. Preferred glycosylases include uracil N-glycosylase (UNG), hypoxanthine-DNA glycosylase, and 3-methyladenine-DNA glycosylases I and II. The most preferred glycosylase in accordance with present invention is UNG. UNG is commercially available (Column 9, lines 4-19)." By employing scientific reasoning, an ordinary artisan would have combined and substituted the uracil specific base cleavage mediated by uracil-N-glycosylase of Sutherland et al. into the computerized mass spectrometry to assess DNA sequence polymorphisms of Kamb in view of Koster in order to improve the sequencing of nucleic acids containing unconventional bases. An ordinary practitioner would have been motivated to combine and substitute the uracil specific base cleavage mediated by uracil-N-glycosylase of Sutherland et al. into the computerized mass spectrometry to assess DNA sequence polymorphisms of Kamb in view of Koster in order to achieve the express advantages noted by Sutherland et al., of a preferred glycosylase UNG which is commercially available and useful to specifically cleave unconventional bases.

9. Claims 1-5, 8-9, 11-13, 15, 24-28 and 31-32 are rejected under 35 U.S.C. 103 (a) over Kamb (U.S. Patent 5,869,242) (February 9, 1999) in view of Caprioli (U.S. Patent 5,808,300) (September 15, 1998)further in view of Sutherland et al. (U.S. Patent 5,985,619) (November 16, 1999).

Kamb in view of Caprioli teach the method of claims 1-5, 8-9, 11-13, 24-28 and 31-32 as described above.

Kamb in view of Caprioli do not teach the method wherein the base specific cleavage is uracil specific and mediated by uracil-N-glycosylase.

Sutherland et al. teach the method wherein the base specific cleavage is uracil specific and mediated by uracil-N-glycosylase (Column 9, lines 4-29).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the uracil specific base cleavage mediated by uracil-N-glycosylase of Sutherland et al. into the computerized mass spectrometry to assess DNA sequence polymorphisms of Kamb in view of Caprioli, since Sutherland et al. state, "The glycosylase useful in the present invention are those that specifically cleave unconventional bases, i.e., bases other than A,G,C or T in DNA and A,G,C and U in RNA. Glycosylases that specifically cleave unconventional bases such as N-& methylguanine, 3-methyladenosine, uracil and hypoxanthine are known to one of ordinary skill in the art. Preferred glycosylases include uracil N-glycosylase (UNG), hypoxanthine-DNA glycosylase, and 3-methyladenine-DNA glycosylases I and II. The most preferred glycosylase in accordance with present invention is UNG. UNG is commercially available (Column 9, lines 4-19)." By employing scientific reasoning, an ordinary artisan would have combined and substituted the uracil specific base cleavage mediated by uracil-N-glycosylase of Sutherland et al. into the mass spectrometry to assess DNA sequence polymorphisms of Kamb in view of Caprioli in order to improve the sequencing of nucleic acids containing unconventional bases. An ordinary practitioner would have been motivated to combine and substitute the uracil specific base cleavage mediated by

uracil-N-glycosylase of Sutherland et al. into the computerized mass spectrometry to assess DNA sequence polymorphisms of Kamb in view of Caprioli in order to achieve the express advantages noted by Sutherland et al., of a preferred glycosylase UNG which is commercially available and useful to specifically cleave unconventional bases.

10. Claims 1-5, 10, 14, 16-18 and 24-28 are rejected under 35 U.S.C. 103 (a) over Kamb (U.S. Patent 5,869,242) (February 9, 1999) in view of Koster (U.S. Patent 6,074,823) (June 13, 2000) further in view of Caprioli (U.S. Patent 5,808,300) (September 15, 1998).

Kamb in view of Koster teach the method of claims 1-5, 10, 14 , 16 and 24-28 as described above.

Kamb in view of Koster do not teach the method of subjecting fragmentation products to further separation by the post source decay method.

Caprioli teaches the method of subjecting fragmentation products to further separation by post source decay method (Column 3, lines 9-11).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a further separation by post source decay method of Caprioli into the computerized mass spectrometry to assess DNA sequence polymorphisms of Kamb in view of Koster, since Caprioli states, "The use of post-source decay techniques is shown in order to obtain sequence verification (Column 3, lines 9-11)." By employing scientific reasoning, an ordinary artisan would have combined and substituted a further separation by post source decay method of Caprioli into the computerized mass

spectrometry to assess DNA sequence polymorphisms of Kamb in view of Koster in order to improve the sequencing of nucleic acids. An ordinary practitioner would have been motivated to combine and substitute a further separation by post source decay method of Caprioli into the computerized mass spectrometry to assess DNA sequence polymorphisms of Kamb in view of Koster in order to achieve the express advantages, as noted by Caprioli, of a method which is used in order to obtain sequence verification.

Response to Amendment

11. In response to amendment, 112 (second paragraph) rejections are hereby withdrawn. However, all 102 and 103 rejections made in the last office actions are hereby being maintained.

Response to Arguments

12. Applicant's arguments filed on March 1, 2002, have been fully considered but they are not persuasive.

Applicant argues that Kamb reference should be withdrawn from 102 (e) rejection because Kamb does not teach "base specific cleavage" and it teaches only "sequence-specific cleavage".Applicant argues that Kamb reference does not teach the "base specific cleavage" of the claimed invention. Applicant argues that the word "base specific cleavage" was not found in Kamb reference and only the word "sequence-specific cleavage" is found. Applicant argues that because Kamb has a preferred embodiment of "sequence-specific cleavage", Kamb is limited to

the preferred embodiment. This argument is not persuasive. As MPEP 2123 states "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi,169 USPQ 423 (CCPA 1971)." MPEP 2123 also states " A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories , 10 USPQ2d 1843 (Fed. Cir. 1989)." It is clear that simply because Kamb has a preferred embodiment, this embodiment does not prevent the reference from suggesting broader embodiments in the disclosure and that this does not constitute a teaching away. Although Kamb reference uses "sequence-specific cleavage", the property of "base specific cleavage" is inherently present in this chemically and structurally identical molecule. For example, Kamb clearly teaches that nucleic acids can be digested with uracil-N-glycosidase (Column 4, lines 39-41). Moreover, MPEP 2111 states, "Claims must be given their broadest reasonable interpretation. During patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification". Applicant always has the opportunity to amend the claims during prosecution and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than it is justified. *In re Prater,* 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969)". In this case, any restriction enzymes can be used for "base specific cleavage".

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant then argues the 103 rejection is improper because it is "obvious to try" and lacks a reasonable expectation of success.

With regard to the "obvious to try" argument, The MPEP 2143.02 states "Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. In re Rinehart , 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) (Claims directed to a method for the commercial scale production of polyesters in the presence of a solvent at superatmospheric pressure were rejected as obvious over a reference which taught the claimed method at atmospheric pressure in view of a reference which taught the claimed process except for the presence of a solvent. The court reversed, finding there was no reasonable expectation that a process combining the prior art steps could be successfully scaled up in view of unchallenged evidence showing that the prior art processes individually could not be commercially scaled up successfully.). See also Amgen, Inc. v. Chugai Pharmaceutical Co ., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), cert. denied , 502 U.S. 856 (1991) (In the context of a biotechnology case, testimony supported the conclusion that the references did not show that there was a reasonable expectation of success. 18 USPQ2d at 1022, 1023.); In re O'Farrell , 853 F.2d 894, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (The court held the claimed method would have been obvious over the prior art relied upon because one reference contained a detailed

enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful.)."

There is no evidence of record submitted by applicant demonstrating the absence of a reasonable expectation of success. There is evidence in the Kamb reference of the enabling methodology, the suggestion to modify the prior art, and evidence that a number of different restriction enzymes including uracil-N-glycosidase were actually experimentally studied and found to be functional (Column 4, lines 36-46). This evidence of functionality trumps the attorney arguments, which argues that Kamb reference is an invitation to research, since Kamb steps beyond research and shows the functional product.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessauat reached at (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

March 13, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600